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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACCESS BIO, INC. Plaintiff, v. API VACCINES, LLC; API PHARMA USA LLC; ABACUS PHARMA INTERNATIONAL, LLC; API ABACUS PHARMA INTL, LLC; and VINCENT DEGENNARO, JR., Defendants.	Civil Action No. _____ **VERIFIED COMPLAINT AND JURY DEMAND**

Plaintiff Access Bio, Inc. ("Access Bio"), by way of this Complaint against Defendants API Vaccines, LLC d/b/a API Pharma ("API Pharma"); API Pharma USA LLC ("API Pharma USA"); Abacus Pharma International, LLC ("Abacus"); API Abacus Pharma Intl, LLC ("API Abacus", and together with API Pharma, API Pharma USA, and Abacus, "API"); and Dr. Vincent DeGennaro, Jr. (collectively, the "Defendants") alleges as follows:

NATURE OF THE ACTION

1. Since the start of the COVID-19 pandemic in the United States, fraudsters, scammers, and other bad actors have been capitalizing on Americans' desire to protect themselves

from the virus.[1] This action focuses on one particular type of COVID-19 scam: counterfeit COVID-19 tests. Seeking to capitalize on the high demand for COVID-19 tests, counterfeiters use false labeling to dupe understandably anxious consumers into purchasing unauthorized tests. Defendants are such counterfeiters. They have actively distributed, sold, promoted, and/or attempted to pass off counterfeit and/or spurious imitations of Access Bio's COVID-19 tests, and, upon information and belief, continue to do so to this day.

2. Through this action, Access Bio seeks to enforce its intellectual property rights, and to protect the public from the counterfeit COVID-19 tests being sold by Defendants.

3. Access Bio also seeks to protect the substantial goodwill that it has built in its CareStart trademark, including multiple logos and designs (together, the "CareStart Mark"). The CareStart Mark has been continuously used by Access Bio since at least 2002.

4. On August 12, 2014, the United States Patent and Trademark Office ("USPTO") granted Access Bio a federal registration for the trademark CARESTART, Registration Number 4,584,214, for the following goods and services: "Diagnostic test kits, for clinical and medical laboratory use, comprised of medical diagnostic preparations and diagnostic test strips for use in the field of fertility and cardiovascular and infectious disease; diagnostic test kits, for veterinary use, comprised of medical diagnostic preparations and diagnostic test strips for use in the field of fertility and infectious disease" (the "CARESTART Registration"). The USPTO's CARESTART Registration notes that the CareStart Mark was first used in commerce in November 2002.

5. Since the start of the COVID-19 pandemic in March 2020, Access Bio has invested considerable time and resources developing, manufacturing, advertising, and using the CareStart

[1] *See generally*, FTC, *Protecting Consumers During the COVID-19 Pandemic: A Year in Review* (April 2021), https://www.ftc.gov/system/files/documents/reports/protecting-consumers-during-covid-19-pandemic-year-review/covid_staff_report_final_419_0.pdf.

Mark in the United States to indicate the source, quality, reliability, and accuracy of its COVID-19 tests. The public has come to trust the CareStart Mark as an indicator of the safety, reliability, and efficacy of Access Bio's COVID-19 tests.

6. Throughout the COVID-19 pandemic, Access Bio has manufactured and sold a variety of COVID-19 tests marketed under its CareStart Mark, which are authorized pursuant to Emergency Use Authorizations ("EUAs") granted by the United States Food and Drug Administration (the "FDA"),[2] including antigen (i.e., rapid) tests, polymerase chain reaction ("PCR") tests, and antibody tests. Access Bio's customers associate the CareStart Mark specifically with Access Bio's COVID-19 and other diagnostic tests. The CareStart Mark represents to the public the safety, reliability, accuracy, and quality of the tests bearing the CareStart Mark, and that such tests have received (at a minimum) an EUA from the FDA.

7. Access Bio is the sole manufacturer of *CareStart* COVID-19 tests. To protect its CareStart Mark and to ensure the quality of its products, Access Bio carefully selects its authorized distributors.

8. As a condition of its EUA that allows it to market its *CareStart* COVID-19 tests, Access Bio must identify its authorized distributors to the FDA.

9. None of the Defendants are an authorized distributor of Access Bio products.

10. In October 2020, shortly after receiving an EUA from the FDA, Access Bio began selling its *CareStart* COVID-19 Antigen test (the "Rapid POC Test") to medical professionals,

[2] *See, e.g.*, FDA, *CareStart COVID-19 Antigen Home Test – EUA 210314* (Nov. 22, 2021), https://www.fda.gov/media/151245/download (the "Home Test FDA Authorization Letter"); *see also* FDA, *CareStart COVID-19 Antigen – EUA 202625* (Apr. 12, 2021), https://www.fda.gov/media/142916/download (the "Rapid POC Test FDA Authorization Letter").

enabling medical professionals to test patients for COVID-19 infections at the point of care ("POC").

11. Access Bio invested significant time, effort, and money to develop, manufacture, advertise, and promote the Rapid POC Test to medical professionals, who rely on Access Bio's tests to provide accurate information.

12. In August 2021, Access Bio began manufacturing and selling its *CareStart* COVID-19 Antigen Home Test (the "Home Test," and together with the Rapid POC Test, the "CareStart COVID-19 Tests"), pursuant to a separate FDA EUA. The Home Test can be purchased by consumers directly from a retail outlet without a prescription, allowing them to test themselves for COVID-19.

13. In response to the unprecedented COVID-19 pandemic, and to make the product easily available to the American public, Access Bio invested significant time, effort, and money to develop, manufacture, advertise, and promote the Home Test to retail outlets and individual consumers, who rely on Access Bio's tests to provide accurate information.

14. Defendants have been advertising and selling a rapid COVID-19 antigen test for home use (the "Counterfeit Home Test") and a rapid POC COVID-19 antigen test (the "Counterfeit Rapid POC Test," and together with the Counterfeit Home Test, the "Counterfeit Products") with packaging that fraudulently mimics Access Bio's genuine CareStart COVID-19 Tests' packaging.

15. The Counterfeit Tests have not received EUAs from the FDA, and thus, are not reliable.

16. Defendants are intentionally deceiving retailers, medical professionals, and the American public by selling the Counterfeit Tests.

17. By this action, Access Bio seeks to enjoin Defendants from promoting, distributing, importing, advertising, offering to sell, selling, and/or palming off their Counterfeit Products, or otherwise infringing on and counterfeiting Access Bio's trademarks and valuable goodwill. Access Bio also seeks damages for any and all losses Access Bio has suffered as a result of Defendants' use, misappropriation, and infringement of Access Bio's trademarks and goodwill. Absent injunctive relief, Defendants' use of the CareStart Mark is likely to continue to cause confusion, mistake, and/or deception among Access Bio's customers and to dilute the CareStart Mark, thus causing irreparable injury to Access Bio.

THE PARTIES

18. Plaintiff Access Bio, Inc. ("Access Bio") is a New Jersey corporation and leading diagnostic test manufacturer and distributor in the United States. Access Bio's principal place of business is located in Somerset, New Jersey.

19. Upon information and belief, Defendant API Vaccines, LLC d/b/a API Pharma ("API Pharma") is a Florida limited liability company with its principal place of business in Miami Beach, Florida.

20. Upon information and belief, Defendant API Pharma USA LLC ("API Pharma USA") is a Florida limited liability company with its principal place of business in Miami Beach, Florida. The FDA's database of registered medical device companies contains an entry for an establishment in Miami Beach, Florida identified as API Pharma USA, with a business trade name of API Vaccines LLC, who's owner/operator is API Pharma USA, who's Official Correspondent is Vincent DeGennaro.[3]

[3] FDA, *Establishment Registration & Device Listing* (Apr. 11, 2022), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?rid=273551.

21. Upon information and belief, including the complaint it filed in *Abacus Pharma International, LLC et al. v. Sutherland*, Case No. 3:21-cv-00289 (Apr. 9, 2021 M.D. Tenn.), Defendant Abacus Pharma International, LLC ("Abacus") is a Delaware limited liability company, with its principal place of business in Alexandria, Virginia.

22. Upon information and belief, Defendant API Abacus Pharma Intl, LLC ("API Abacus") is a Florida limited liability company with its principal place of business in Miami Beach, Florida.

23. Upon information and belief Defendant Dr. Vincent DeGennaro, Jr. is a partial owner, Chief Executive Officer ("CEO") and/or Chief Operating Officer ("COO"), and Medical Director of Defendant API Pharma, and resides at 1881 Washington Ave., Apartment 8H, Miami Beach, Florida 33139.

JURISDICTION AND VENUE

24. This Court has jurisdiction over this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338(a), 1338(b).

25. This Court also has jurisdiction over this action pursuant to 28 U.S.C. §1332(a)(1), because the matter in controversy exceeds the sum of $75,000, exclusive of interest and costs, and is between citizens of different States.

26. Venue is proper in the District of New Jersey pursuant to 28 U.S.C. § 1391(b) and (c) because Access Bio resides in this District and a substantial part of the events giving rise to the claim occurred in this District.

27. Defendants are subject to personal jurisdiction in the District of New Jersey because, on information and belief, they are marketing and selling the Counterfeit Products in this

District and have otherwise directed their wrongful conduct towards residents of New Jersey, including Access Bio.

28. Upon information and belief, Defendants maintain a website, accessible to anyone who has access to the Internet, including residents of New Jersey. Defendants' website is https://api-medical.com/. Until shortly before the filing of this Complaint, this website was currently advertising at least one Counterfeit Product. A true and correct image of the page on Defendants' website advertising the Counterfeit Rapid POC Test, as it appeared on March 29, 2022, is attached hereto as **Exhibit A**. On or about April 9, 2022, Defendants' website was replaced with a message that reads, "This site has stepped out for a bit."

FACTUAL ALLEGATIONS

29. Access Bio has continuously promoted its diagnostic tests to medical professionals and individual consumers, as appropriate for the given test, using the CareStart Mark, since at least 2002.

30. Access Bio owns federal Trademark Registration Number 4,584,214 for the trademark CARESTART. The CareStart Mark was registered on August 12, 2014, for the following goods and services: "Diagnostic test kits, for clinical and medical laboratory use, comprised of medical diagnostic preparations and diagnostic test strips for use in the field of fertility and cardiovascular and infectious disease; diagnostic test kits, for veterinary use, comprised of medical diagnostic preparations and diagnostic test strips for use in the field of fertility and infectious disease." The USPTO registration notes that the CareStart Mark was first used in commerce in November 2002. A true and correct copy of the USPTO's Trademark Electronic Search System ("TESS") database entry showing the CARESTART Registration is attached hereto as **Exhibit B**.

31. On July 29, 2020, Access Bio filed affidavits with the USPTO pursuant to Sections 8 and 15 of the Lanham Act (15 U.S.C. §§ 1058, 1065), establishing that the CareStart Mark has been in continuous use for more than five years. The CareStart Mark is therefore incontestable.

32. The CARESTART Registration is owned exclusively by Access Bio and remains in full force and effect. This registration constitutes prima facie evidence of the validity of the CARESTART Registration, of Access Bio's ownership of the mark, and of Access Bio's exclusive right to use the mark in interstate commerce for the goods and services identified.

33. Access Bio devotes substantial time, effort, and resources to developing, manufacturing, advertising, promoting, and obtaining FDA authorizations, or EUAs, for its CareStart diagnostic tests.

34. Access Bio's tests, and particularly its COVID-19 tests, are sold throughout the United States, including in the District of New Jersey.

35. As a result of its extensive and continuous use of the CareStart Mark, through advertising and in connection with the packaging, sale, and use of CareStart diagnostic tests, Access Bio has developed substantial goodwill in the CareStart Mark, which enjoys a strong reputation among consumers. The CareStart Mark has also acquired secondary meaning in that it is immediately associated in the minds of the public and medical professionals with Access Bio and its high quality, FDA authorized, diagnostic tests.

Access Bio's CareStart COVID-19 Tests

36. Access Bio is the only manufacturer of genuine CareStart COVID-19 Tests, which are authorized for sale in the United States pursuant to FDA EUAs. Access Bio carefully selects its authorized distributors.

37. Medical professionals and individual patients alike rely upon the accuracy and validity of Access Bio's CareStart COVID-19 Tests during the ongoing COVID-19 public health crisis. Access Bio has built a reputation amongst its customers that its CareStart COVID-19 Tests are safe, reliable, and authorized by the FDA for emergency use in the United States.

38. Within the past few months, Access Bio learned that Defendants were advertising, importing, attempting to sell, and/or actually selling, the Counterfeit Products. For example, one of Access Bio's customers shared with the Company a letter with enclosures dated December 1, 2021. The letter is on API Pharma USA's letterhead and is signed by Defendant DeGennaro (the "DeGennaro Letter"). A true and correct copy of the December 1, 2021 DeGennaro Letter, including the enclosures, is attached hereto as **Exhibit C**. In the letter, Defendant DeGennaro wrote to non-party Kent Fleck of ClearChem Diagnostics, Inc.:

> API Vaccines LLC dba API Pharma hereby confirm [sic] that ClearChem Diagnostics, Inc and Kent Fleck are a [sic] Joint Venture Partner for the Access Bio CareStart Point of Care test (20/box) and Access Bio CareStart Home test (2/box). Please note on the following page that ***API Pharma is an authorized distributor of Access Bio CareStart products***. Please also note on page three that the parent company of Access Bio USA is Access Bio Korea and they have authorized sales of their product in the USA.

Ex. C at 1 (emphasis added).

39. The DeGennaro Letter contains numerous falsehoods:

- API Pharma lacks any authority to create a "Joint Venture Partner[ship]" for any CareStart COVID-19 Tests;
- API Pharma is not an authorized distributor of CareStart COVID-19 Tests. In fact, Access Bio has never authorized API Pharma, nor any of the Defendants, to distribute any of its CareStart COVID-19 Tests;
- "Access Bio Korea" is not the "parent company of Access Bio USA"; and

- Neither Access Bio nor Access Bio Korea, Inc. ("ABK"), which is a wholly-owned subsidiary of Access Bio, "have authorized sales of [ABK's] product in the USA."

40. The first enclosure to the DeGennaro Letter, Ex. C at 2, purports to be a "Letter of Declaration," dated August 9, 2021, and signed by ABK's CEO and President. This "Letter of Declaration" is a forgery.

41. ABK's then-CEO and President, Dr. Jay Do Choi, never made any of the alleged statements in the "Letter of Declaration." *See generally*, Affidavit of ABK CEO and President, Dr. Jay Do Choi, dated April 11, 2022 ("Choi Aff."), which is filed concurrently with this Complaint.

42. Dr. Choi did not write, sign, authorize his signature to be placed on, or otherwise authorize the "Letter of Declaration" to be issued. Choi Aff., ¶ 6.

43. Dr. Choi did not have the authority to sign a "Letter of Declaration," or any other documents on behalf of ABK, in August 2021. *Id.*, ¶ 7.

44. Even if Dr. Choi did have the authority to sign such a "Letter of Declaration" in August 2021, which he did not, it would be highly unusual for him to sign such a document. Authentic authorization letters of this kind would be signed by a senior official in ABK's Regulatory Affairs Department. *Id.*, ¶ 9.

45. ABK does not send "letters of declaration" as proof of permission for third parties to market, sell, and otherwise distribute ABK's products. Rather, ABK sends "letters of appointment" to entities it permits to market, sell, and otherwise distribute its products. *Id.*, ¶ 10.

46. Upon information and belief, Defendants (and particularly Defendant DeGennaro) created this forged "Letter of Declaration" in an effort to legitimize the lies contained in the DeGennaro Letter. *See* Ex. C at 1–2.

47. Further evidence of the forged nature of the purported "Letter of Declaration" is the fact that ABK's name is incorrectly written as "ACCESS BIO KOREA INC." in three places: (1) at the top of the page in the supposed letterhead, (2) in the first full sentence, and (3) below the signature line. ABK's full company name is Access Bio Korea, Inc. (as shown in the stamp next to the signature line, which was likely copied and pasted from another document), and not "ACCESS BIO KOREA INC." (without the comma) as the forged "Letter of Declaration" asserts. *Id.* at 2; *see also* Choi Aff., ¶¶ 11–12.

48. The letterhead depicted in the forged "Letter of Declaration" is not the letterhead ABK was using in August 2021. Choi Aff., ¶¶ 11–12. This is evidenced, in part, by the incorrect company name ("ACCESS BIO KOREA INC.") and irregular abbreviation and capitalization in the country designation ("Rep. of KOREA"). *Id.*, ¶ 12.

49. In addition to the various indicia of forgery noted above, the substance of the "Letter of Declaration" is inconsistent with how ABK conducts its highly regulated diagnostic testing business. *Id.*, ¶ 13. ABK would never grant a blanket permit to a company such as API Pharma to export its "Antigen test kits" to the United States, without any oversight or quality control. *Id.*

50. Pursuant to the Federal Food, Drug, and Cosmetic Act and related regulations, manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. 21 U.S.C. § 360j(f); 21 C.F.R. § 820. The quality systems for FDA-regulated products are known as current good manufacturing practices ("cGMPs"). The FDA generally expects that EUA products will be produced, stored, and

distributed in compliance with cGMPs.[4] Because Access Bio's products cannot be legally marketed unless quality control is maintained, any authorization Access Bio grants must have appropriate quality controls to ensure continued compliance with regulatory requirements. *See id.*; *see also* Choi Aff., ¶ 13.

51. Access Bio, not ABK, manages all import and export agreements and licenses for diagnostic tests being shipped to the United States, since Access Bio, not ABK, holds the EUAs for CareStart COVID-19 Tests. *Id.*, ¶ 14; *see also* Rapid POC Test FDA Authorization Letter & Home Test FDA Authorization Letter. Thus, ABK would never issue a "Letter of Declaration" or a letter of appointment to any third party.

52. Finally, neither Access Bio nor ABK would allow a third party, like API Pharma, to "paste their sticker on our box for their clients," as this would violate the FDA's cGMPs requirements, which require manufacturers to "establish and maintain procedures to control labeling activities," to "control labeling and packaging operations to prevent labeling mixups," and to print and apply labels "so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use." 21 C.F.R. § 820.120. Similar requirements govern ABK's diagnostic tests in numerous other countries. Choi Aff., ¶ 15; *see also* EU Medical Device Regul. ("MDR") 2017/745; Int'l Org. for Standardization ("ISO") 13485.

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[4] *See* FDA, *Emergency Use Authorization of Medical Products and Related Authorities – Guidance for Industry and Other Stakeholders*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities (Jan. 2017), § (E)(5)(a).

53. Upon information and belief, Defendants created the forged "Letter of Declaration" on fraudulent letterhead with the specific intent to defraud potential customers and convince them to buy the Counterfeit Products.

The Counterfeit Products

54. Defendants have been advertising and attempting to sell at least two counterfeit Access Bio CareStart COVID-19 Tests: the Counterfeit Rapid POC Test and the Counterfeit Home Test.

55. Access Bio carefully selects the authorized distributors of its CareStart COVID-19 Tests in the United States. No Defendant named in this action is one of those authorized distributors.

56. As a condition of its EUAs authorizing it to market its CareStart COVID-19 Tests, Access Bio is required to identify its authorized distributors to the FDA. *See* Rapid POC Test FDA Authorization Letter & Home Test FDA Authorization Letter.

57. The FDA database indicates that Defendant API Pharma USA is registered solely as a "U.S. Manufacturer of Export Only Devices."[5] The FDA database also indicates that Defendant API Pharma has only listed one device with FDA, the "API Pharma Covid-Rapid IgM/IgG Rapid Antibody Test; HIGHTOP 2019-nCoV IgG/IgM Rapid Test Cassette."[6] No other Defendants have registered with the FDA.

58. Thus, to the extent any Defendant has any FDA medical device authorization at all, it is only to manufacture devices for export, not to sell devices within the United States. Moreover,

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5 FDA, *Establishment Registration & Device Listing*, *supra.*

6 FDA, *Establishment Registration & Device Listing* (Apr. 11, 2022), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm?lid=688785&lpcd=QKO.

failure to properly register with the FDA as a manufacturer, repackager, or importer of devices is a violation of Section 301(p) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(p).

59. Access Bio and its authorized distributors are required to comply with numerous FDA requirements. For example, the Rapid POC Test FDA Authorization Letter requires Access Bio and its authorized distributors to, among other things, comply with certain FDA labeling requirements. These labeling requirements include: (1) stating adequate directions for use and appropriate limitations on use; (2) providing the FDA-authorized labeling to authorized testing laboratories; (3) providing the FDA-authorized labeling on their respective websites, (4) including a physical copy of the FDA-authorized "Quick Reference Instructions for CareStart COVID-19 Antigen" and "CareStart COVID-19 Antigen Package Insert (Instructions for Use)" with each COVID-19 test; (5) maintaining inventory records showing the number of tests distributed and the authorized laboratories to whom they were distributed to; and (6) reporting to the FDA on the performance of the product, including any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the Rapid POC Test.

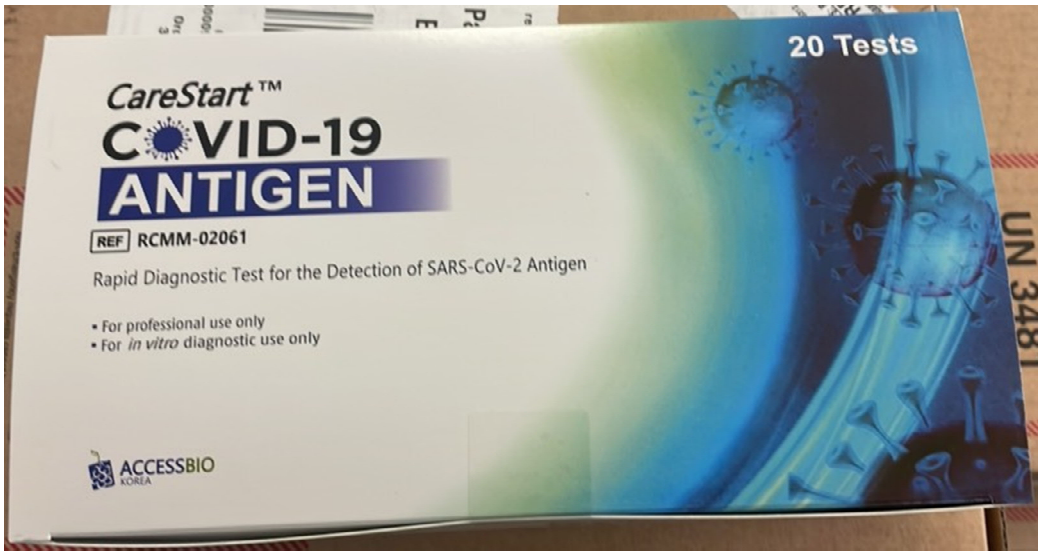
60. Similarly, the Home Test FDA Authorization Letter requires Access Bio and its authorized distributors to, among other things: (1) include adequate directions for use and appropriate limitations on use in each test package; (2) provide the "CareStart COVID-19 Antigen Home Test User Instructions" and the "Fact Sheet for Individuals" in each package, (3) maintain customer complaint files, and report to the FDA any significant complaints about usability or deviations from the established performance characteristics of the test that Access Bio and authorized distributors become aware of; (4) maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) where tests are distributed and the number of tests distributed to each

location; and (5) report to the FDA on the performance of the product, including any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test. Access Bio has not received any communications from any of the Defendants regarding its compliance with any of these regulatory requirements, which the FDA has established to ensure proper use of these tests and protect the health and safety of the individuals who use them.

Defendants' Counterfeit Rapid POC Tests

61. Access Bio's Rapid POC Test, which received an EUA from the FDA, is sold in a pack of 20 tests. The distinctive blue and white packaging indicates that the tests are made in the United States by Access Bio, and the Rapid POC Tests are permitted for: (1) use under an EUA only, (2) professional use only, and (3) in vitro diagnostic use only. The package also clearly states that the Rapid POC Tests are "Rx Only." A true and correct picture of Access Bio's genuine Rapid POC Test packaging is below.

62. The Counterfeit Rapid POC Tests Defendants are marketing and selling fraudulently mirror many of the distinctive elements of Access Bio's Rapid POC Test. The Counterfeit Rapid POC Tests include substantially identical blue and white packaging, logos, and imagery, including the CareStart Mark, and are also sold in packs of 20 tests. However, the counterfeit packaging omits or changes information critical to potential purchasers of the Counterfeit Rapid POC Tests. The counterfeit packaging does not state that the tests are only available for use under an EUA, nor that they are for prescription use only. The counterfeit packaging also does not indicate that the Counterfeit Rapid POC Tests were manufactured in the United States. The counterfeit packaging features an unauthorized copy of ABK's logo, rather than Access Bio's logo. A true and correct photograph of the Counterfeit Rapid POC Test packaging being sold by Defendants is below.



63. Defendants have advertised the Counterfeit Rapid POC Test on their website at https://api-medical.com/accessbio-antigen-test/. The image on Defendants' website has been a low-resolution photograph of a genuine Access Bio Rapid POC Test, rather than the counterfeit tests Defendants are actually selling and delivering to customers.

64. Defendants' Counterfeit Rapid POC Tests appear to be packaged with and/or contain components and parts that Defendants have impermissibly obtained. They may contain genuine components purchased overseas from ABK, but any tests purchased directly from ABK are not permitted for sale or use in the United States because they have not received an EUA. A true and correct copy of the FDA's website listing COVID-19 antigen tests with EUAs, as of March 31, 2022, is attached hereto as **Exhibit D**.[7]

65. Even if the Counterfeit Rapid POC Tests are partially or wholly comprised of genuine, albeit unauthorized, ABK components, Access Bio is unable to guarantee the accuracy and reliability of those components because it has no visibility into, or control over, the chain of distribution. Without controlling the chain of distribution for the Counterfeit Rapid POC Tests, Access Bio does not know if the Counterfeit Rapid POC Tests were transported and/or stored at the proper temperature, or if they have otherwise been compromised while under Defendants' control.

66. Upon information and belief, Defendants' Counterfeit Rapid POC Tests are either (a) ABK tests which Defendants are impermissibly acquiring, repackaging,[8] and then selling in the United States, or (b) kits containing test components from unknown sources and packaged by Defendants for sale in packaging featuring the counterfeit CareStart Mark, in an attempt to deceive purchasers into thinking they are buying genuine Access Bio Rapid POC Tests. Either way,

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[7] The list can also be accessed directly from the FDA's website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#iaft1; *see also* FDA, *Coronavirus (COVID-19) and Medical Devices* (Feb. 22, 2022), https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices.

[8] Authentic *CareStart* COVID-19 Ag tests manufactured by ABK are packaged in green and white (rather than blue and white) packaging and clearly state that they are "NOT FOR SALE IN THE U.S.A."

Defendants are selling counterfeit COVID-19 tests that have not received an EUA from the FDA, and may have been compromised while under Defendants' control. These counterfeit and misbranded medical devices are putting Americans' health and safety at risk.

Defendants' Counterfeit Home Tests

67. Defendants' Counterfeit Home Tests contain many of the same defects as their Counterfeit Rapid POC Tests, making it clear that that the Counterfeit Home Tests are not genuine CareStart COVID-19 Tests.

68. The packaging for the Counterfeit Home Test features the same purple, white, and yellow packaging as Access Bio's Home Test, including a counterfeit CareStart Mark.

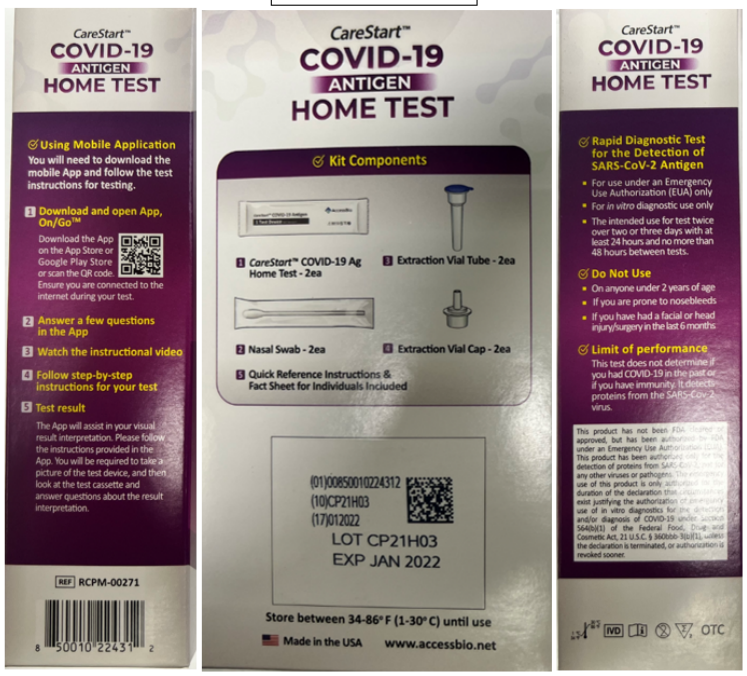
69. Defendants' Counterfeit Home Test, however, does not contain a UPC Code, and lists "Access Bio Korea, Inc.," as opposed to "Access Bio, Inc.," as the manufacturer on the infringing packaging.

70. Like the Counterfeit Rapid POC Test, Defendants' Counterfeit Home Test packaging also does not state that the product was "Made in the USA."

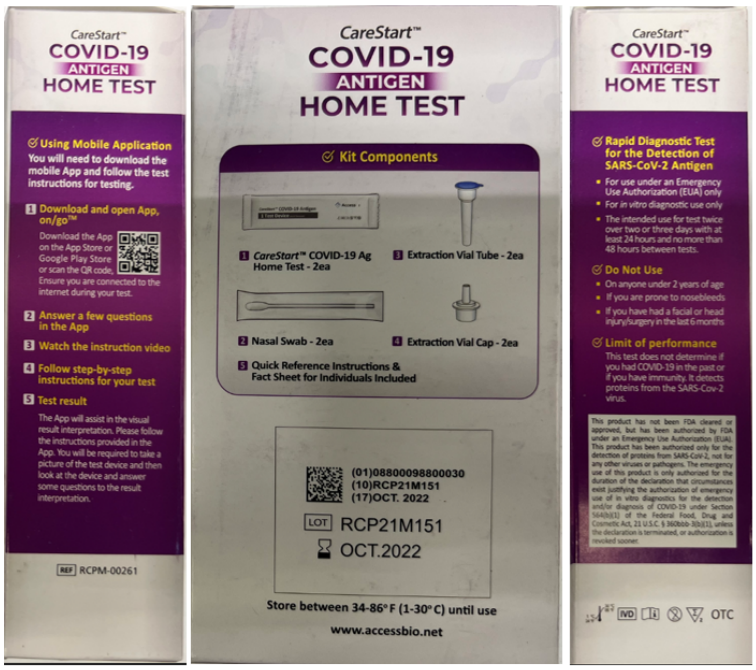
71. The Counterfeit Home Test also fraudulently states that it received an EUA from the FDA, which it did not. No COVID-19 antigen test manufactured by ABK has received an EUA. *See* Ex. D at 2–3.

72. True and correct images of the Access Bio Home Test and Defendants' Counterfeit Home Test are below.

Access Bio Home Test



Counterfeit Home Test



73. Defendants' Counterfeit Home Tests appear to be packaged with and/or contain components and parts that have been impermissibly obtained. They may contain genuine components purchased overseas from ABK, but any tests purchased directly from ABK are not permitted for sale or use in the United States because they have not received an EUA.

74. Even if the Counterfeit Home Tests are partially or wholly comprised of genuine, albeit unauthorized, ABK components, Access Bio is unable to guarantee the accuracy and reliability of those components because it has no visibility into, or control over, the chain of distribution. Without controlling the chain of distribution for the Counterfeit Home Tests, Access

Bio does not know if the Counterfeit Home Tests were transported and/or stored at the proper temperature, or if they have otherwise been compromised while under Defendants' control.

75. Upon information and belief, Defendants' Counterfeit Home Tests are either (a) ABK tests which Defendants are impermissibly acquiring, repackaging, and then selling in the United States, or (b) kits containing test components from unknown sources packaged by Defendants and offered for sale in packaging featuring the counterfeit CareStart Mark, in an attempt to deceive purchasers into thinking they are buying genuine Access Bio Home Tests. Either way, Defendants are selling counterfeit COVID-19 tests that have not received an EUA from the FDA, and may have been compromised while under Defendants' control. These counterfeit and misbranded medical devices are putting Americans' health and safety at risk.

76. The FDA's online list of COVID-19 antigen tests that have received EUA makes clear that only tests sold by Access Bio, and not any tests sold by ABK, are authorized for sale and use in the United States at this time. *See* Ex. D.

The Counterfeit Products are Causing Customer Deception and Confusion

77. In an apparent effort to capitalize on consumer recognition and usurp the goodwill associated with the CareStart Mark and Access Bio's reputation, Defendants have deliberately modeled the packaging for their Counterfeit Products to closely mimic the packaging found on genuine CareStart COVID-19 Tests.

78. Defendants' Counterfeit Products are not merely likely to cause confusion among Access Bio's current and prospective customers; they have already caused actual customer confusion. Access Bio learned of Defendants' fraudulent conduct and the Counterfeit Products from multiple sources, including an Access Bio customer who reached out to inquire about the

authenticity of the Counterfeit Home Test. An Access Bio customer contacted the company to lodge a quality and accuracy related complaint about a Counterfeit Product they had purchased.

79. The Counterfeit Products are falsely labeled and/or advertised with unauthorized imported components, creating quality, reputational, and compliance risks for Access Bio, in addition to a significant public health risk. Counterfeit COVID-19 tests, which did not receive EUA, may be unreliable, produce inaccurate results, and thereby undermine the very purpose of COVID-19 testing.

80. Defendants' marketing of the Counterfeit Products in packaging that is nearly identical to Access Bio's packaging, and their unauthorized use of the CareStart Mark, is tarnishing, and will continue to tarnish, the goodwill and value associated with Access Bio's CareStart COVID-19 Tests and CareStart Mark.

81. Defendants' Counterfeit Products travel in the same channels of trade as the CareStart COVID-19 Tests. The genuine and Counterfeit Products will be used by the same classes of consumers, and the Counterfeit Products will cause customers and potential customers to wrongly associate Defendants' Counterfeit Products with Access Bio's genuine CareStart COVID-19 Tests. Defendants' actions will also cause customers to assume that the Counterfeit Products emanate from, or are authorized, licensed, or otherwise affiliated with Access Bio.

82. Upon information and belief, this was Defendants' specific intent, as evidenced by the DeGennaro Letter, in which Defendant DeGennaro falsely claimed that API Pharma is an authorized distributor of Access Bio's Home Test and Rapid POC test. *See* Ex. C at 1.

83. Upon information and belief, Defendants' continued fraudulent and infringing actions evidence their attempt to take advantage of Access Bio's goodwill and intellectual property rights. Defendants' actions have been, and, unless enjoined, will continue to be, in violation of

federal and state law governing trademark infringement and unfair competition. Defendants are causing immediate and irreparable harm to Access Bio, including lost customers, revenues, and goodwill, in addition to loss of control over its reputation.

Defendants Ignored Access Bio's Previous Requests to Stop Selling the Counterfeit Products

84. On January 24, 2022, counsel for Access Bio sent a letter to Defendant DeGennaro, as the representative of Defendant API Pharma, notifying him that the Counterfeit Home Test infringed Access Bio's intellectual property rights and was likely to cause significant harm to Access Bio (the "Polsinelli Letter").

85. A true and correct copy of the Polsinelli Letter is attached here to as **Exhibit E**.

86. The Polsinelli Letter demanded, inter alia, that Defendants, by February 11, 2022, cease and desist from dealing in the Counterfeit Home Test, disclose where the Counterfeit Home Tests had been distributed, account for all units of the Counterfeit Home Test, and certify the destruction of all Counterfeit Home Tests in Defendants' possession.

87. Defendants ignored the Polsinelli Letter.

88. Access Bio did not hear about Defendants selling any counterfeit or fraudulent Access Bio products again until approximately March 10, 2022, when Access Bio learned that Defendants were selling the Counterfeit Rapid POC Tests.

89. On April 12, 2022, counsel for Access Bio sent another letter to Defendant DeGennaro, as the representative of Defendant API Pharma (the "Lowenstein Letter"), notifying Defendants that Access Bio had learned of additional misconduct since the Polsinelli Letter. Specifically, the Lowenstein Letter notified Defendants that Access Bio was aware of Defendants' advertising and selling of the Counterfeit Rapid POC Tests, and that litigation was likely to follow.

90. A true and correct copy of the Lowenstein Letter is attached hereto as **Exhibit F**.

91. The Lowenstein Letter demanded that Defendants preserve all documents related to the Counterfeit Products.

92. Defendants have not responded to the Lowenstein Letter.

COUNT I

Federally Registered Trademark Infringement and Use of a Counterfeit Mark Pursuant to 15 U.S.C. §§ 1114 and 1116(d)

93. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

94. Access Bio is the exclusive owner of the CareStart Mark for use in connection with diagnostic test kits.

95. Defendants knowingly, and without the consent of Access Bio, have sold and continue to sell the Counterfeit Products, which feature nearly identical packaging and imitations of Access Bio's CareStart COVID-19 Tests (including the CareStart Mark) in interstate commerce, and are thus likely to cause, and actually have caused, confusion, mistake, and/or deception among consumers.

96. Defendants' Counterfeit Products use a counterfeit CareStart Mark, within the meaning of 15 U.S.C. § 1116(d)(1)(B).

97. Notwithstanding Access Bio's established rights in the CareStart Mark and the CareStart COVID-19 Tests, Defendants distribute, promote, and sell counterfeit and/or otherwise spurious knock-off Counterfeit Products, in or affecting interstate commerce, in direct competition with the sale of genuine CareStart COVID-19 Tests.

98. Upon information and belief, Defendants intend to deceive customers into believing that the Counterfeit Products are Access Bio's genuine CareStart COVID-19 Tests.

99. Defendants' activities constitute counterfeiting and intentional, willful infringement of Access Bio's rights under 15 U.S.C. § 1114, and have caused and will continue to cause Access Bio irreparable harm.

100. Access Bio has no adequate remedy at law as monetary damages are inadequate to compensate it for the injuries caused by Defendants.

101. Unless immediately restrained and enjoined by this Court pursuant to 15 U.S.C. § 1116(a) and (d) and the equitable powers of this Court, Defendants will persist in their activities and continue to cause Access Bio irreparable harm.

102. Access Bio is entitled to injunctive relief, including the seizure of Counterfeit Products in Defendants' possession.

103. Access Bio has suffered damages, including lost profits, which will be proven at trial.

104. In addition, and/or in the alternative, Access Bio is entitled to disgorgement and recovery of Defendants' profits from their sales of the Counterfeit Products after an accounting thereof.

105. Alternatively, pursuant to 15 U.S.C. § 1117(c), Access Bio is entitled to statutory damages. Specifically, because Defendants' counterfeiting activity is and was willful, Access Bio is entitled to statutory damages for each counterfeit usage of the CareStart Mark.

106. Because of Defendants' counterfeiting and willful, malicious, and/or fraudulent misconduct, and/or because of the exceptional nature of this case, Access Bio is entitled to enhanced (or treble) damages under 15 U.S.C. § 1117(c), and/or an award of costs and reasonable attorneys' fees under 15 U.S.C. § 1117(a).

107. Defendants' acts are causing and will continue to cause Access Bio irreparable harm in the nature of lost sales and revenue, loss of control over its reputation, and loss of substantial consumer goodwill. This irreparable harm to Access Bio will continue, without any adequate remedy at law, unless and until Defendants' unlawful conduct is enjoined by this Court.

COUNT II

Use of a Counterfeit Mark Pursuant to N.J.S.A § 56:3-13.16

108. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

109. Access Bio is the exclusive owner of the CareStart Mark under federal law and common law for use in connection with diagnostic test kits.

110. Defendants knowingly, and without the consent of Access Bio, have sold and continue to sell the Counterfeit Products, which feature nearly identical packaging and imitations of Access Bio's CareStart COVID-19 Tests (including the CareStart Mark), and are thus likely to cause, and actually have caused, confusion, mistake, and/or deception among consumers.

111. Notwithstanding Access Bio's established rights in the CareStart Mark and the CareStart COVID-19 Tests, Defendants distribute, promote, and sell counterfeit and/or otherwise spurious knock-off Counterfeit Products, in direct competition with the sale of genuine CareStart COVID-19 Tests.

112. Without prejudice to the generality of the foregoing, Defendants' violations consist of and/or include the use of counterfeit and spurious marks, in connection with the sale, offering for sale, and/or distribution of the Counterfeit Products.

113. Upon information and belief, Defendants intend to deceive customers into believing that the Counterfeit Products are Access Bio's genuine CareStart COVID-19 Tests.

114. Defendants' activities constitute counterfeiting and intentional, willful infringement of Access Bio's rights, and have caused and will continue to cause Access Bio irreparable harm.

115. Access Bio has no adequate remedy at law as monetary damages are inadequate to compensate it for the injuries caused by Defendants.

116. Unless immediately restrained and enjoined by this Court, Defendants will persist in their activities and continue to cause Access Bio irreparable harm.

117. Access Bio is entitled to injunctive relief, including the seizure and/or disposal of Counterfeit Products in Defendants' possession.

118. Access Bio has suffered damages, including lost profits, which will be proven at trial.

119. In addition, and/or in the alternative, Access Bio is entitled to disgorgement and recovery of Defendants' profits from their sales of the Counterfeit Products after an accounting thereof.

120. Because of Defendants' counterfeiting and willful, malicious, and/or fraudulent misconduct, and/or because of the exceptional nature of this case, Access Bio is entitled to enhanced (or treble) damages and/or an award of costs and reasonable attorneys' fees

121. By virtue of the foregoing, Defendants' acts are causing and will continue to cause Access Bio irreparable harm in the nature of lost sales and revenue, loss of control over its reputation, and loss of substantial consumer goodwill. This irreparable harm to Access Bio will continue, without any adequate remedy at law, unless and until Defendants' unlawful conduct is enjoined by this Court.

COUNT III

Federally Registered Trademark Infringement Pursuant to 15 U.S.C. § 1125(a)

122. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

123. Through its efforts in the United States market, Access Bio has developed extensive goodwill in its federally registered CareStart Mark, as used in connection with diagnostic tests, including COVID-19 tests, and is the sole owner of such mark and all goodwill in the CareStart Mark.

124. Defendants have used the CareStart Mark in interstate commerce, without authorization from Access Bio, to falsely advertise the availability of Access Bio's products through their website and in communications with prospective customers throughout the United States.

125. Defendants' unauthorized use of Access Bio's trademark is likely to cause, and has actually caused, confusion, mistake, and/or deception among consumers as to the affiliation, connection, or association between Access Bio and Defendants. Such activity constitutes trademark infringement, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

126. Access Bio has suffered irreparable harm and damages as a direct and proximate result of the wrongful acts of Defendants, in that Defendants' activities have willfully caused confusion among consumers in the market for at-home and point of care COVID-19 tests.

127. As a direct and proximate cause of Defendants' infringement, Access Bio has suffered, and will continue to suffer, substantial damages and irreparable harm.

128. Defendants will, on information and belief, continue to infringe upon Access Bio's rights under §43(a) of the Lanham Act unless and until they are enjoined by this Court. Access

Bio has been and is likely to continue to be injured unless Defendants are enjoined. Access Bio has no adequate remedy at law.

COUNT IV

False Designation of Origin and False or Misleading Description of Fact Pursuant to 15 U.S.C. § 1125(a)

129. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

130. Defendants' use of fake imitations of the CareStart COVID-19 Tests has been intentional and willful. Defendants' bad faith is evidenced at least by the striking similarity of the Counterfeit Products to Access Bio's genuine CareStart COVID-19 Tests. Additionally, the use of identical logos, fonts, color scheme, names, and nearly identical packaging, demonstrate the intentional and willful nature of Defendants' actions.

131. Defendants' statements, particularly "that API Pharma is an authorized distributor of Access Bio CareStart products," Ex. B at 1, is a false representation of fact which, in commercial advertising or promotion, misrepresents the nature, characteristics, and qualities of Access Bio's goods and services, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125.

132. The Counterfeit Products offered for sale or sold by Defendants are not genuine products, and are likely materially different from the genuine CareStart COVID-19 Tests sold by Access Bio through its authorized distributors.

133. The Counterfeit Products have been impermissibly distributed in the United States by Defendants and/or other parties acting in concert with Defendants, without Access Bio's knowledge or consent.

134. Because Defendants distribute the Counterfeit Products outside of Access Bio's vetted and supervised distribution chain, the Counterfeit Products may not produce accurate or

reliable results due to Defendants' failure to properly control the temperature of the Counterfeit Products during transport and storage, or otherwise mishandling sensitive medical devices.

135. Defendants' Counterfeit Products, which lack FDA authorization, are likely to deceive consumers into believing that Access Bio's genuine CareStart COVID-19 Tests are not reliable, accurate, and FDA-authorized products.

136. Defendants are deceiving customers by selling the fraudulent Counterfeit Products, which are not authorized for sale in the United States, and which may not provide accurate results.

137. Upon information and belief, as a result of Defendants' false and misleading statements, sales of the Home Test and Rapid POC Test have been diverted from Access Bio and their authorized distributors to Defendants' Counterfeit Products. Access Bio has suffered and will continue to suffer from loss of customers and public trust. These injuries are irreparable.

COUNT V
False Designation of Origin and False or Misleading Description of FDA Authorization Pursuant to 15 U.S.C. § 1125(a)

138. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

139. By selling or offering to sell fraudulent and non-FDA authorized COVID-19 tests, which include the CareStart Mark, Defendants have attempted to pass off the Counterfeit Products as if they were genuine COVID-19 tests manufactured and legally distributed by Access Bio in the United States.

140. The accuracy, dependability, and EUA of Access Bio's COVID-19 tests are material to customers' purchasing decisions.

141. The Counterfeit Products offered for sale or sold by Defendants are not genuine products, and are likely materially different from the genuine CareStart COVID-19 Tests sold by Access Bio through its authorized distributors.

142. The Counterfeit Products have been impermissibly distributed in the United States by Defendants and/or other parties acting in concert with Defendants, without Access Bio's knowledge or consent.

143. Because Defendants distribute the Counterfeit Products outside of Access Bio's vetted and supervised distribution chain, the Counterfeit Products may not produce accurate or reliable results due to Defendants' failure to properly control the temperature of the Counterfeit Products during transport and storage, or otherwise mishandling sensitive medical devices.

144. Defendants' Counterfeit Products, which lack FDA authorization, are likely to deceive consumers into believing that Access Bio's genuine CareStart COVID-19 Tests are not reliable, accurate, and FDA-authorized products.

145. Defendants are deceiving customers by selling the fraudulent Counterfeit Products, which are not authorized for sale in the United States, and which may not provide accurate results.

146. Upon information and belief, as a result of Defendants' false and misleading statements, sales of Access Bio's Home Test and Rapid POC Test have been diverted from Access Bio and its authorized distributors to Defendants' Counterfeit Products. Access Bio has suffered and will continue to suffer from loss of customers and public trust. These injuries are irreparable.

COUNT VI
Unfair Competition Pursuant 15 U.S.C. § 1125(a)

147. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

148. Defendants have, in connection with sales of the Counterfeit Products in interstate commerce, falsely claimed to be selling Access Bio's COVID-19 tests. Defendants have made such claims with full knowledge of the falsity of such statements, to the detriment of Access Bio.

149. In particular, Defendants' unauthorized and fraudulent efforts to sell the Counterfeit Products, featuring the CareStart Mark, and falsely claiming to be an authorized distributor for Access Bio, constitute the use of false descriptions and representations.

150. The activities of Defendants complained of herein have been and continue to be conducted in bad faith and constitute willful and intentional conduct.

151. Defendants' actions violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

152. As a direct and proximate cause of Defendants' actions, Access Bio has suffered and will continue to suffer substantial damages and irreparable harm. Access Bio has no adequate remedy at law.

COUNT VII

Unfair Competition Pursuant to N.J.S.A § 56:4-1 and Common Law

153. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

154. Defendants' use of the CareStart Mark, without the authorization or consent of Access Bio, is likely to cause confusion and mistake and to deceive customers as to the source of origin of the Counterfeit Products. Customers and potential customers are likely to believe that Defendants' Counterfeit Products are manufactured, licensed, authorized, affiliated, or otherwise connected with Access Bio, which they are not.

155. Defendants' actions appropriate Access Bio's name, brand, CareStart Mark, reputation, and goodwill for their own use, in violation of the New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq.*

156. Defendants' conduct has been willful and deliberate, with the intent to deceive customers and potential customers into believing that the Counterfeit Products are genuine CareStart COVID-19 Tests.

157. Defendants' Counterfeit Products are causing immediate and irreparable harm to Access Bio.

158. Access Bio has no adequate remedy at law sufficient to fully remedy Defendants' conduct, and unless Defendants are enjoined from continuing to sell or attempting to sell the Counterfeit Products, they will continue to cause Access Bio irreparable harm.

159. Access Bio has been and will continue to be harmed by Defendants' conduct in an amount subject to proof.

COUNT VIII
Common Law Trademark Infringement

160. Access Bio repeats and realleges each and every allegation contained in each of the foregoing paragraphs as if set forth fully herein.

161. Access Bio has continuously used the CareStart Mark in interstate commerce since at least 2002, including within New Jersey.

162. As a result of the substantial and continuous use of CareStart Mark, consumers in New Jersey and throughout the country, associate the CareStart Mark with Access Bio's diagnostic tests, and particularly, its COVID-19 tests.

163. Defendants' use of CareStart Mark, and Access Bio's logos and product line names, is likely to cause mistake or confusion of customers, potential customers, and others as to the source, authenticity, reliability, and accuracy of Access Bio's COVID-19 tests.

164. Defendants have infringed Access Bio's common law trademark rights in the CareStart Mark.

165. Access Bio has suffered, and will continue to suffer, damages, in an amount to be proven at trial, as a result of Defendants' wrongful infringement of the CareStart Mark.

166. Access Bio's legal remedies are inadequate to make them whole. Access Bio has suffered, and will continue to suffer, irreparable harm to its goodwill and reputation unless Defendants are enjoined from their wrongful acts.

PRAYER FOR RELIEF

WHEREFORE, with respect to all Causes of Action set forth in this Complaint, Plaintiff Access Bio US, Inc. respectfully requests that this Court:

a) Grant preliminary and permanent injunctive relief enjoying and restraining Defendants, and their officers, directors, agents, servants, employees, licensees, and all other persons in privity or acting in concert with them from:

i) Using the CareStart Mark or other Access Bio designations or any term, mark, logo, trade name, or any other source identifier, symbol of origin, or packaging design that is confusingly similar to the CareStart Mark or likely to dilute its distinctive quality;

ii) Advertising, promoting, selling, or offering for sale any of the Counterfeit Products or other products bearing the CareStart Mark; and

iii) Falsely representing or suggesting that the products Defendants purport to sell or offer for sale under the CareStart Mark or Access Bio logo are genuine, or are authorized or emanate from Access Bio, or from otherwise falsely advertising, representing or suggesting any connection with Access Bio;

b) Require Defendants to:

i) Cancel all outstanding orders of the Counterfeit Products and to refund any monies received;

ii) Notify all customers that it is not an authorized distributor of Access Bio's COVID-19 tests and is not associated with, sponsored, by or otherwise affiliated with Access Bio; and

iii) Issue a recall of all of the Counterfeit Products that Defendants have shipped to its customers;

c) Order that Defendants account to Access Bio for its profits and any damages sustained by Access Bio from the foregoing acts of trademark infringement, trademark dilution, and unfair competition;

d) Order an award of profits in accordance with such accounting and award a judgment for three times Access Bio's actual damages arising from Defendants' unlawful conduct pursuant to 15 U.S.C. § 1117;

e) Find that Defendants' conduct was willful and that this case is exceptional pursuant to 15 U.S.C. § 1117;

f) Order that Access Bio recover its costs including its reasonable attorney's fees and disbursements in this action pursuant to 15 U.S.C. § 1117;

g) Order that any products, brochures, advertisements, signs, and any other written or printed or electronic material in Defendants' possession, custody or control that bears the CareStart Mark or Access Bio logo be delivered up to Access Bio for destruction, pursuant to 15 U.S.C. § 1118;

h) Grant any and all relief provided pursuant to N.J.S.A. § 56:4-2, including treble damages;

i) Order that Defendants and their officers, directors, agents, servants, employees, licensees, and all other persons in privity or acting in concert with them take affirmative steps to dispel any actual confusion that heretofore has been created by the trademark infringement described above; and

j) Order any such other and further relief as the Court deems just, proper, and equitable.

Dated: April 14, 2022

LOWENSTEIN SANDLER LLP

By: */s/ David Leit*

David Leit
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Attorney for Plaintiff
Access Bio US, Inc.

JURY DEMAND

Access Bio hereby demands trial by a jury as to all issues of fact.

DESIGNATION OF TRIAL COUNSEL

David Leit, Esq. is hereby designated as trial counsel for Plaintiff Access Bio US, Inc. in the within matter.

By: */s/ David Leit*

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Attorney for Plaintiff Access Bio US, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is not the subject of any other action or proceeding pending in any court or arbitration.

Dated: April 14, 2022

By: */s/ David Leit*
David Leit

VERIFICATION

I, Seonghwan Park, of full age, hereby verify:

1. I am the Quality Assurance ("QA") Manager of Plaintiff Access Bio, Inc.

2. I have read the forgoing Complaint and Jury Demand, and, except where matters are stated to be based upon information and belief, or where matters are based upon information in the Affidavit of Dr. Jay Do Choi, I verify that the allegations contained therein are true, to the best of my personal knowledge and belief.

3. As to the allegations made upon information and belief, I believe those to be true.

I verify, under the penalty of perjury, that the foregoing statements are true and correct. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

Dated: April 13, 2022

SEONGHWAN PARK

CERTIFICATION OF SERVICE

I, the undersigned certify that on this date I forwarded a copy of the within pleading to all counsel of record by CM/ECF.

Dated: April 14, 2022

By: */s/ David Leit*
David Leit